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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: L. Whiteside

GROUP ART UNIT: 3308

SERIAL NO.: 08/466,607

EXAMINER: B. Snow

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FOR: Acetabular Component With Improved Liner Seal and Lock

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

AMENDMENT A

SIR:

In response to the Office action dated September 11, 1995, applicant requests entry of the following amendments:

In the Claims

a1 1. (Amended) In a prosthesis including a shell having screw holes therein, and a liner which is received by said shell, the improvement comprising a seal between said shell and liner to restrict migration of foreign material between said liner and shell to said screw holes.

ax 5. (Amended) The prosthesis of Claim 4 wherein said shell includes a relatively flat surface for receiving said at least one ridge.

sub B 6. (Amended) The prosthesis of Claim 5 wherein each of said at least one ridges is an annulus integrally formed on said liner, and said surface is sized and spaced to receive

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Jan. 11, 1996  
Date of Signature

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3 (cont.)  
a2 (cont.)  
all of said at least one ridges, said seal thereby restricting migration of foreign material from outside of said shell/liner interface to the [interior of said shell/liner interface] screw holes.

7. (Amended) The prosthesis of Claim 5 wherein [said shell includes at least one opening and] said seal extends annularly around the liner [surrounds said at least one openings] to thereby prevent foreign material from passing [therethrough] to the screw holes.

a3 B  
10. (Amended) The prosthesis of Claim 9 wherein [said] each notch includes a pair of [notches include] protruding lips to grasp said tabs as they engage.

a4  
13. (Amended) An acetabular component including a generally hemispherically shaped shell having screw holes therein and a generally hemispherically shaped liner for being received in said shell, and a seal between said liner and shell for restricting migration of foreign material between said liner and said shell to said screw holes.

a5  
15. (Amended) The acetabular component of Claim 14 wherein said seal includes a plurality of annular shaped ridges formed on said liner and said shell includes [an] a relatively flat inner surface [upon] against which said ridges rest as said liner seats in said shell to thereby sealingly engage said liner to said shell.

#### REMARKS

Claim 1, particularly as amended herewith, is believed to be patentable over Tronzo, and is also believed to be patentable over Tronzo in view of Muller.

Claim 1 requires a prosthesis which includes (1) a shell having screw holes therein, (2) a liner which is received in the shell, and (3) a seal between the shell and liner to restrict the passage of foreign matter between the liner and the shell to the screw holes. The problem which arises in the prior art from debris migration is discussed on page 1, line 12 to page 2, line 34 of the present application.

Tronzo clearly does not meet the requirements of claim 1 concerning screw holes. As shown in Figs. 4 and 5 of Tronzo the shell of the Tronzo device has no screw holes at

all. Instead, it is fastened in place by a series of exterior, jagged ribs 56. Tronzo, therefore, does not even address the problem solved by the present invention. The annular rings 52 and 54 in Tronzo are provided for connecting liner 46 to shell 44 -- not for sealing the shell/liner interface to prevent migration of debris therebetween to the screw holes, from where they can cause damage to the bone. Thus, the structures relied on the Examiner in Tronzo are not seals at all, as also required by claim 1.

It should be noted that Muller, the secondary reference, while it does have screw holes, does not suggest the present invention. Muller utterly lacks the claimed seal between the shell and the liner. An examination of Figs. 1 and 2 reveal an open path between the shell and the liner practically the entire distance from the screw hole 6 to the exterior of the device. Moreover, Muller is completely silent concerning prevention of debris migration to the screw holes.

If Tronzo and Muller have any teaching of how to prevent migration of debris to the screw holes of a prosthesis, that teaching is found in Tronzo. And Tronzo eliminates the problem of debris migration to the screw holes by eliminating the screw holes. Such a structure does not meet the requirements of claim 1. Tronzo, to the extent that it is relevant, therefore, teaches away from the present invention.

Claim 1 is allowable for all these reasons.

Claim 2 depends from claim 1 and is allowable therewith. In addition, claim 2 provides that the liner substantially conforms to and contacts the shell under load bearing conditions, and that the seal maintains its sealing engagement between the liner and the shell under load bearing conditions. As noted above, Tronzo has no seal (and has no need of one). An inspection of Muller (Figs. 1 and 2) reveals that under load bearing conditions the only parts of the liner which are in contact with the shell are subject to movement, thereby promoting the very migration of debris which the present invention is designed to prevent. Claim 2 is allowable for these reasons as well.

Claim 3 depends from claim 2 and is allowable for the same reasons as that claim. Moreover, claim 3 requires that the seal includes at least one ridge of resilient material so that load bearing contact between the liner and the shell brings the ridge into sealing engagement. Tronzo does not show such a feature, and neither does Muller.

Claim 4 depends from claim 3 and is allowable therewith. It further specifies that the ridge is formed as part of the liner.

Claim 5 depends from claim 4 and further provides that the shell includes a relatively flat surface for receiving the sealing ridge(s). This is surface 53 in Fig. 2 in the present application. Note that even if Tronzo had a seal (which it does not), the "ridge" of that "seal" is not disposed against a relatively flat surface as in the present claim. Rather in Tronzo, the ridge of the liner is disposed in a groove. This difference further highlights the differences between Tronzo and the present invention. Of course, Muller completely lacks this feature as well. For all these reasons, claim 5 is allowable over these references.

Claim 6 depends from claim 5 and is allowable for the same reasons as that claim. Claim 6 further specifies that the ridge(s) are received on a single surface of the shell. This is not shown in either Tronzo or Muller.

Claim 7 is also dependent on claim 5 and further requires that the seal extends annularly around the liner to prevent debris from passing to the screw holes. As noted above in connection with claim 1 in more general terms, neither Tronzo nor Muller have such a feature.

Claims 8 - 10 relate back to claim 1 and are allowable therewith. In addition, claim 10 provides that each notch of the tab and notch system includes a pair of protruding lips to grasp the tabs. These are lips 78, 80 shown in Fig. 3 in the present application. Such a structure is not shown in Tronzo or Muller.

Claim 11 depends from claim 1 and further requires an interlock between the liner and the shell. If Tronzo shows a seal (which it does not), then where is the interlock? The

Examiner takes the position that ring 48 in Tronzo is the seal and ring 50 and groove 54 are the interlock. Tronzo, however, makes absolutely no such distinction between rings 48 and 50. It is respectfully submitted that such a distinction arises not from the reference but from improper hindsight. Claim 11 is allowable for this reason as well.

Claim 12 depends from claim 11 and is allowable for the same reasons as that claim.

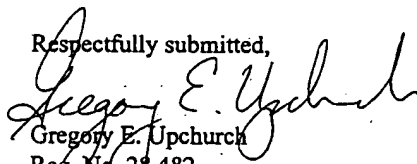
Claim 13 is an independent claim directed to an acetabular component having, among other things, a shell with screw holes therein and a seal for restricting migration of foreign material between the liner and the shell to the screw holes. As discussed above in connection with claim 1, these features are absent from Tronzo and are also absent from Muller.

Claim 14 depends from claim 13 and is allowable therewith. This claim further requires that the liner is shaped to seat along substantially its entirety with the shell, and that the seal maintains sealing engagement between the liner and seal as the liner seats in the shell. As discussed above, these features are absent from these references.

Claim 15 depends from claim 14 and is allowable for the same reasons as that claim. In addition, claim 15 provides that the seal includes a plurality of annular shaped ridges, and that the shell includes a relatively flat inner surface against which the ridges rest. This feature, as discussed above, is also absent from Tronzo and Muller.

In view of the above, favorable reconsideration and a notice of allowability of claims 1 - 15 is solicited.

Respectfully submitted,

  
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